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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/501,102

Applicant(s)

CO ET AL

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 143-160 is/are pending in the application.
- 4a) Of the above claim(s) 143, 144, 148 and 155-160 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 145-147 and 149-154 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1644

### DETAILED ACTION

1. Applicant's election with traverse of Group II is acknowledged. The traversal is on the ground(s) that the examination of the entire application would not constitute a burden to search. This is not found persuasive because the inventions are distinct and require non-coextensive searches as noted in the last Office Action, as shown by the distinctness described therein

The requirement is still deemed proper and is therefore made FINAL.

Alternatively, applicant is invited to submit evidence or identify such evidence now of record showing the Groups or species to be obvious variants or clearly admit on the record that this is the case.

Claims 145-147 and 149-154, as they read on the elected invention / species are under consideration in the instant application.

Upon reconsideration of the prior art, the species election has been extended to include both cyclosporine and rapamycin in the claimed methods.

Claims 143-144, 148 and 155-160 have been withdrawn from further consideration by the examiner, 37 C.F.R. 1 § 1.142(b) as being drawn to a nonelected inventions and species.

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

Applicant should update the status of the priority documents on the first line of specification.

3. The filing date of the instant claims is deemed as follows.

While It appears that priority USSN 09/249,011 provides for combining "immunoglobulins specific to B7-1 / B7-2" or treating transplant recipients with certain immunosuppressive agents, the instant claims do not appear to have the priority date of USSNs 09/339,596 and 09/249,011.

There appears to be insufficient written description for the phrase of "at least one" in the context of the "immunoglobulin specific to B7-1 / B7-2 / calcineurin inhibitor, steroid and immunosuppressive agent that arrest the growth of immune cells, methotrexate, CD40 pathway inhibitor, transplant salvage pathway inhibitor, IL-2 receptor antagonist, and analogs thereof", "cyclosporin A or FK506 (non-elected "methyl prednisone or prednisone").

Art Unit: 1644

Also, priority USSN 09/249,011 does not appear to provide sufficient written description for the recitation of all of the inhibitors recited in claims 146-149 and 154 as well as the dosing regimens recited in instant claims 150-154.

Therefore, given the lack of written description of the claimed methods as indicated herein and below, the instant claims do not appear to have the priority date of USSNs 09/339,596 and 09/249,011.

If applicant desires priority back to their priority documents, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Given the number of continuation-in-part applications, applicant is invited to clarify the support under 35

A claim as a whole has only one effective filing date.

See Studiengesellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Obviousness is not the standard for the addition new limitations to the disclosure as filed.

It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1644

7. Claims 145-147 and 149-154 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: the phrase of "at least one" in the context of the "immunoglobulin specific to B7-1 / B7-2 / calcineurin inhibitor, steroid and immunosuppressive agent that arrest the growth of immune cells, methotrexate, CD40 pathway inhibitor, transplant salvage pathway inhibitor, IL-2 receptor antagonist, and analogs thereof", "cyclosporin A or FK506 (non-elected "methyl prednisone or prednisone").

Applicant's Preliminary Amendment, filed 10/02/02, asserts that no new matter has been added and relies upon the disclosure of certain pages of the instant specification for support of newly added claims, including the recitation of "at least one".

However, the recitation of "at least one" is not readily apparent either in the pending or in the earlier priority applications.

There appears to be insufficient written description for the phrase of "at least one" in the context of the "immunoglobulin specific to B7-1 / B7-2 / calcineurin inhibitor, steroid and immunosuppressive agent that arrest the growth of immune cells, methotrexate, CD40 pathway inhibitor, transplant salvage pathway inhibitor, IL-2 receptor antagonist, and analogs thereof", "cyclosporin A or FK506 (non-elected "methyl prednisone or prednisone").

It appears that applicant relies upon a generic description of combining various immunosuppressive agents together.

However, the claims as currently recited also encompass multiple species of each immunosuppressive agent as currently claimed and

not limited to combining different immunosuppressive agents, as described in the instant and priority applications as filed

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

The specification as filed does not provide a sufficient written description or set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitation", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Art Unit: 1644

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above.  
See MPEP 714.02 and 2163.06

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Since the priority date of the instant claims may be in question the following rejection are made under 35 U.S.C. § 102 (b)(e), as it would apply to the priority of the instant claims.

10. Claims 145-147 and 149-154 are rejected under 35 U.S.C § 102(b)(e) as being anticipated by Sayegh et al. (U.S. Patent No. 6,280,957) (see entire document).

Sayegh et al. teach methods of inhibiting transplant rejections, including combinations with one or more antibodies directed against B7-1 and B7-2 (e.g. see column 1, lines 55-61) in combination with other immunosuppressive agents such as cyclosporin A and rapamycin (e.g. see column 4, paragraph 2) as well as dosing and modes of administration, including at the time of transplant and post-transplant immunosuppressive regimens (E.g. see columns 2-3, overlapping paragraph and column 5, paragraph 1) that anticipate the instant methods (see entire document, particularly Summary of the Invention and Claims).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

11. No claim allowed.

Art Unit: 1644

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, Ph.D., J.D.

Primary Examiner

Technology Center 1600

March 3, 2006